Message

From: Strauss, Linda [Strauss.Linda@epa.gov]
Sent: 9/4/2015 2:36:33 PM
To: Jones, Jim [Jones.Jim@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]; Sterling, Sherry [Sterling.Sherry@epa.gov]; Mojica, Andrea [Mojica.andrea@epa.gov]; Dunton, Cheryl [Dunton.Cheryl@epa.gov]
Subject: FW: Chicago Tribune Investigative Reporter on 2,4-D in food

Here's what I sent OPA

From: Strauss, Linda
Sent: Friday, September 04, 2015 10:36 AM
To: Milbourn, Cathy
Cc: Hull, George
Subject: RE: Chicago Tribune Investigative Reporter on 2,4-D in food

Cathy, here is our response:

When EPA makes a decision on any pesticide, the agency's number one concern is protecting human health by meeting the standard of reasonable certainty of no harm from dietary and residential exposure. EPA's decisions related to 2,4-D meet this standard and the agency is confident that the use of 2,4-D is safe for all people, due to the sound science that is the basis of all of EPA's regulatory decisions. Risk assessments are based on the best available science and protective assumptions that exaggerate anticipated exposure to the chemical in question.

FIFRA, as amended by FQPA, recognizes the fact that scientific understanding is constantly evolving and, as we continue to learn and get better studies to help us understand the potential impacts of exposure to chemicals, our conclusions about risk change. Sometimes a new study tells us we need to strengthen limitations; sometimes it goes the other way.

In the case of 2,4-D, the new state-of-the-art science clearly indicated that 2.4-D is less toxic than our earlier, older assessment. The new data included a new study that addresses numerous potential toxic effects, not in only one or two age groups, but over an entire lifespan, across generations and sexes. With this new data, we have more confidence, more precision in our assessment. We now have a complete and robust database, and as provided by FQPA

As of now, EPA is the first governing body to make any decisions on 2,4-D based on this new study. It is EPA's understanding that other governments do agree with our interpretation of the new study, but have not yet incorporated the results into their 2,4-D reviews.

Regarding the potential for use of 2,4-D on corn and soybeans to increase, it is important to note that while EPA does its assessments based on the very conservative assumption that all crops grown would be eaten by people, *the majority of the crops (corn and soybeans) are used for animal feed*, thus decreasing any human exposure even more. Some of these crops are also used for processed foods (example: corn syrups) and as a result of processing, the risk of exposure is greatly reduced.

Let me explain in more detail how allowable dietary levels are established. First, the safe level of 2,4-D in food and drinking water (as well as residential exposure) is determined based on scientific studies that indicate an exposure level at which no toxic effects are seen in laboratory animals. This No Observed Adverse Effect Level (NOAEL) is then divided by a number of safety factors to ensure that those exposed are protected. These

safety factors take into account differences between laboratory animals and humans (10-fold factor), and the potential differences in sensitivity among different people (10-fold factor). Additionally, if there are special concerns for effects in infants and children, an additional 10-fold safety factor is employed (FQPA safety factor).

Prior to 2013, the NOAEL used to determine a safe exposure level was 5 mg/kg/day, with toxic effects not observed until a dose of 75 mg/kg/day; many toxic effects were seen at this dose level including blood, thyroid, liver, testes, ovarian, and lung toxicity. This was divided by all 3 safety factors described (10 x 10 x 10 = 1000-fold safety factor). The FQPA safety factor had been added because of missing toxicity data, which introduced uncertainty into the Agency's risk assessment; these missing data included reproductive, comparative thyroid, and immunotoxicity studies. The final safe level was therefore determined to be 0.005 mg/kg/day (5/1000).

However, prior to the most recent risk assessment, the missing toxicity data were submitted as part of a study which assessed all of the potential toxic effects for which data were previously missing in both adult and young animals, in addition to other information such as data on how 2,4-D is absorbed, distributed, metabolized, and excreted from the body. This state of the art scientific study (called the Extended One Generation Reproductive Toxicity Study, or EOGRTS) measures a host of scientific effects across ages, generations, and sexes, and addresses numerous toxic effects that potentially could have occurred as a result of 2,4-D exposure. It should be noted that this specific 2,4-D study was discussed on multiple occasions by the Organisation for Economic Development and Cooperation (OECD) Expert Group on Reproductive Toxicity during its adoption of the study's guideline, and so has received extensive peer review by experts from around the world. The dose at which no toxicity was observed for this study was 21 mg/kg/day, with effects seen at 47 mg/kg/day. The previous NOAEL of 5 mg/kg/day that had been used to determine a safe level for 2,4-D reflects the large gap (15-fold) between the doses tested in the older study (5 mg/kg/day *vs.* 75 mg/kg/day effect level); thus, the NOAEL was an artifact of the dose selection for the study, and could more accurately be determined with better toxicity data. The new data collected as part of the study allow the agency to more precisely estimate the No Observed Adverse Effect Level (NOAEL) and the Lowest Observed Adverse Effect Level (LOAEL).

With this new, high quality study, combined with the already extensive 2,4-D database, the toxicity potential for 2,4-D was thoroughly assessed. The 10X FQPA safety factor must be applied in cases where EPA does not have a complete data set. In this case, the dataset is complete and very robust, and the 10X was reduced to 1X based on reliable data. Although the Agency is confident that its decision to reduce the FQPA safety factor is scientifically sound and consistent with established science policy, in order to more fully characterize risk potential, we also assessed risks retaining the 10X FQPA safety factor. Risks were *still* acceptable for all age groups for all components of the assessment: dietary food and drinking water exposure, volatility, spray drift, residential, and aggregate assessment. Additionally, the study allowed a more precise estimate of the level at which no toxic effects would occur, moving from the previously estimated 5 mg/kg/day, to 21 mg/kg/day, roughly a 4-fold increase. These two factors combined - the increased dose showing no toxic effects and the removal of the additional safety factor - led to an approximately 40-fold increase in the amount of exposure deemed to be safe.

Since the FQPA safety factor had originally been applied to address uncertainties related to missing toxicity studies, and this new study filled that gap, we determined that the 100-fold (10 x 10) safety factor was sufficient to protect all age groups. Additionally, the study allowed a more precise estimate of the level at which no toxic effects would occur, moving from the previously estimated 5 mg/kg/day, to 21 mg/kg/day, roughly a 4-fold increase. These two factors combined - the increased dose showing no toxic effects and the

removal of the additional safety factor - led to an approximately 40-fold increase in the amount of exposure deemed to be safe.

To summarize, EPA's judgement that 2,4-D is less toxic than indicated by our older assessment is supported by a refined estimate of toxicity based on the new, state-of-the-science toxicity study.

Regarding exposure, the Agency conducts all of its assessments in a manner to ensure that any foreseeable exposure to a pesticide chemical is accounted for. Specifically for 2,4-D, the Agency used high quality data to estimate maximum 2,4-D levels in foods and drinking water in its assessment. The Agency also assumed that all food crops that could be treated with 2,4-D, would be treated, and would be treated at the maximum allowable rates. These data and assumptions greatly exaggerate any exposures that might actually occur, but were used to ensure that normal use of the pesticide would be safe. For potential 2,4-D exposure from use on home lawns, the Agency again used high quality data and a combination of exposure assumptions that exaggerate any exposure likely to occur from use of the pesticide. Finally, the Agency added together all of these overstated exposure assumptions (food, drinking water, and home lawn use exposures) to estimate risks for all those potentially exposed: infants, children, pregnant women, and those with differing diets, lifestyles, and sensitivities, and determined that there will be no risk from the use of this chemical.

You also mention the changes in the conclusions of the toxicity review of the extended one-generation reproductive toxicity study. This is important for 2 reasons. First the changes were made following a more in-depth review of the specific toxic effects and the relationship among related effects seen in the study. This resulted in the Agency determining that adverse effects were not observed at 21 mg/kg/day, but were observed at the next higher dose of 47 mg/kg/day. This was not based on any change in policy, but was based on a more integrated and comprehensive consideration of the study results. Second, this change was made in consultation with EPA's international partners, including expert scientists from Canada's Pest Management Regulatory Agency, who concurred on the modification to the estimated level at which no adverse toxic effects were observed. It should be emphasized that the state of the art EOGRTS study is a recently submitted study, and not all international regulatory agencies have yet incorporated the results into their regulation of this chemical.

From: Milbourn, Cathy
Sent: Monday, August 31, 2015 8:12 PM
To: Strauss, Linda; Sisco, Debby
Cc: Milbourn, Cathy
Subject: Fw:Chicago Tribune Investigative Reporter on 2,4-D in food

Linda: here's what the reporter is interested in.

Cathy,
Thanks for taking my call. As we discussed, my story looks at your agency's decision to allow 41 times more 2,4-D in food and water than the amount allowed by the EPA under the administration of President George W. Bush. You had asked that I put some key points in writing so that you could find the right EPA officials to answer questions and comment on my investigation.

The broader context of my story is how the latest generation of genetically modified crops is resurrecting weed killers of generations past. I am not focusing on the altered DNA in the crops themselves; rather, I am looking on the farm chemicals these crops enable.

EPA's own estimates of dietary exposure show that if Dow's new genetically modified crops are widely adopted, American toddlers, preschoolers and elementary school children could ingest on a regular basis levels of 2,4-D in food and water considered dangerous by EPA scientists for decades - exceeding the allowable levels set under every administration dating back to Ronald Reagan's presidency. Indeed, day to day people of all ages unwittingly could ingest 2,4-D at levels that the Bush administration considered unsafe. Kids between the ages of 1 an 12 could be exposed chronically to levels of 2,4-D the World Health Organization considers unsafe. Not only could young children exceed Canada's chronic allowable level of 2,4-D, but the most exposed toddlers could exceed the level Canada sets for just one day's exposure. The USDA anticipates a nearly seven-fold increase in the amount of 2,4-D sprayed on corn and soybeans if Dow's new genetically modified crops are widely adopted. Had the EPA kept the dietary protections set in 2005, I don't believe the EPA would have been able to clear the increased use of 2,4-D for Dow's new genetically modified corn and soybeans. I would like to interview the EPA officials who made the decision to raise the chronic reference dose from 0.005 mg/kg to 0.21 mg/kg and get a better sense of what went into that decision. My story looks at how those allowable dietary levels are set and what this means for public health since 2,4-D has been linked to a wide array of health problems.

As we discussed, I also am interested in talking to Dr. Linda Taylor about her review of the Dow Extended One Generation Reproduction study and her later revision of that review.

I would also like to speak with the EPA official who wrote the answer to Question 11 in the Enlist Duo FAQs. If that person is unavailable, I would like to speak someone who is familiar with the concepts discussed in Question 11. ("11. Did EPA take into account the 10x safety factor specified under the Food Quality Protection Act to protect children?") Here is a link to the FAQs:

http://www2.epa.gov/ingredients-used-pesticide-products/registration-enlist-duo#10x factor

As you can see, I'd like to speak with the scientists who have intimate knowledge of these decisions, but I'd also like the broader view of EPA leadership on this key public health issue. For that reason, I am requesting an interview with Administrator Gina McCarthy. In addition to the issues I outlined above, I was hoping she would address the concerns raised by Dr. Philip Landrigan in this recent New England Journal of Medicine editorial:

http://www.nejm.org/doi/full/10.1056/NEJMp1505660?rss=searchAndBrowse&

As you probably know, Dr. Landrigan chaired the National Academy of Sciences panel on pesticides in the diets of children, and it was that panel's grave warnings that led Congress to pass the Food Quality Protection Act in the mid-1990s. Dr. Landrigan was also one of the first scientists to document the brain damage caused by childhood lead poisoning, work that persuaded the EPA to ban lead from gasoline and paint in the 1970s. Last year, he was so alarmed by the dramatic increase in 2,4-D the EPA was allowing into the American diet that he urged Administrator McCarthy to reverse her decision on Enlist Duo. In this editorial, he argues that the EPA failed to follow the federal pesticide law that his National Academy of Sciences panel inspired. I'd like to give Administrator McCarthy a chance to respond.

I look forward to speaking with you and your EPA colleagues this week. If you have any questions, please don't hesitate to call me in my office at (312)222-3898 or on my cell at (312)752-5505.

Many thanks,

Trish

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